

Attorney Docket No.: DC-0156  
Inventors: DeLeo and Weinstein  
Serial No.: 09/857,385  
Filing Date: July 6, 2001  
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**REMARKS**

Claim 1 is pending in this application. Claim 1 has been rejected. Claim 1 has been amended. Reconsideration is respectfully requested in light of the following remarks.

**I. Rejection of Claims Under 35 U.S.C. 103(a)**

The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (1996) has been maintained. The Examiner suggests that Applicants arguments regarding this reference were not persuasive since Mori et al. teach that doses of 3 mg/kg or greater provide a weak analgesic effect and that applicant does not claim a specific dosage range thus this reference makes obvious use of methotrexate for relief of pain, including the claimed pain type. Applicants respectfully traverse this rejection.

Applicants respectfully point out again that this reference at best, supports the analgesic activity of methotrexate only at specific doses and only in response to specific types of pain. The paper teaches that the analgesic effects of the drug are limited at best. Nowhere does this paper teach or suggest that methotrexate is capable of preventing or reducing lower back pain with

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radiculopathy as claimed. To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. The fact that the teachings of Mori et al. are mixed in terms of the type of pain involved would not allow one of skill in the art to understand and expect that lower back pain with radiculopathy could be successfully treated. Accordingly, this paper cannot make obvious the instant invention which is limited to a specific type of pain response. However, in an earnest effort to advance the prosecution, Applicants have further amended claim 1 to specify that the dose of methotrexate administered is below 3 mg/kg. Support for this amendment to the claims can be found at page 8 of the specification as filed. Based on this further amendment to claim 1, the paper of Mori et al. (1996) also fails to teach the limitations of the claims. Accordingly, this paper cannot establish a *prima facie* case of

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obviousness and withdrawal of this rejection is respectfully requested.

## **II. Objection to the Claim**

Claim 1 has been objected to as missing the term of "need" when referring to a method of treatment. Applicants have amended the claim language as requested by the Examiner and withdrawal of this objection is respectfully requested.

## **III. Rejection of Claims Under 35 U.S.C. 112, First Paragraph**

Claim 1 has been rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The Examiner suggests that while being enabling for a method of treatment of lower back pain with radiculopathy does not reasonably provide enablement for preventing such pain. In an earnest effort to advance the prosecution, Applicants have amended claim 1 to remove the term "prevent". Withdrawal of this rejection is therefore respectfully requested.

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#### **IV. Rejection of Claims Under 35 U.S.C.**

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by Chamberlain et al. (1997). The Examiner suggests that this abstract discloses radiculopathy is treated *inter alia* with methotrexate and that the open claim language of comprising leaves open use of inclusion of unspecified ingredients, even in major amounts. Applicants respectfully traverse this rejection.

At the outset, claim 1 has been amended to recite that the method of the invention involves use of doses of methotrexate for relief of pain that are below 3 mg/kg, and that the method "consists of" use of use of methotrexate. Nowhere does the cited reference teach or suggest use of the claimed doses of methotrexate, by themselves, for relief of pain. In order to anticipate an invention, the cited reference must teach each and every limitation of the claims (MPEP 2131). Accordingly, this reference cannot anticipate the claims as amended. Withdrawal of this rejection is respectfully requested.

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by Leger et al. (1992). The Examiner suggests that this paper discloses treatment of a polyradiculopathy in an AIDS patient with *inter alia* methotrexate. As discussed *supra*, claim 1

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has been amended to recite that the method of the invention involves use of doses of methotrexate for relief of pain that are below 3 mg/kg, and that the method "consists of" use of use of methotrexate. Nowhere does the cited reference teach or suggest use of the claimed doses of methotrexate, by themselves, for relief of pain. In order to anticipate an invention, the cited reference must teach each and every limitation of the claims (MPEP 2131). Accordingly, this reference cannot anticipate the claims as amended. Withdrawal of this rejection is respectfully requested.

Claim 1 has been rejected under 35 U.S.C. 120(b) as being anticipated by O'Neill et al. (1997). The Examiner suggests that this paper discloses a patient with NIDDM and painful polyradiculopathy that improved with use of a treatment that included methotrexate. Again, as discussed *supra*, claim 1 has been amended to recite that the method of the invention involves use of doses of methotrexate for relief of pain that are below 3 mg/kg, and that the method "consists of" use of use of methotrexate. Nowhere does the cited reference teach or suggest use of the claimed doses of methotrexate, by themselves, for relief of pain. In order to anticipate an invention, the cited reference must teach each and every limitation of the claims (MPEP 2131). Accordingly,

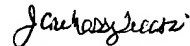
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this reference cannot anticipate the claims as amended. Withdrawal of this rejection is respectfully requested.

#### V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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